U.S. Food and Drug Administration
Q-Submissions Program for Medical Devices
OMB Control Number 0910-0756

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" (https://www.fda.gov/media/114034/download) provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with the Food and Drug Administration (FDA) regarding certain potential or planned medical device submissions, as well as issues conveyed in certain submission hold letters and IDE letters reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submissions Types and other uses of the Q-Submission Program.

2. Purpose and Use of the Information

The information collected will support a structured process with clear recommendations for sponsors who submit Q-Submissions, for FDA staff and managers involved in their review, and for expected timeframes for providing written feedback and scheduling meetings. The guidance includes recommendations for the information to be submitted as part of a Q-Submission and the timeframes in which FDA intends to provide the requested feedback. The guidance also includes recommendations for sponsors regarding how to prepare for meetings with FDA staff.

3. Use of Information Technology and Burden Reduction

We estimate that approximately 98 percent of respondents will complete the information collection using electronic means.

For CDRH-regulated products, in accordance with section 745A(b) of the Food, Drug, and Cosmetic Act (FD&C Act), respondents must submit an eCopy.[1] For more information about the eCopy program, please see the FDA guidance "eCopy Program for Medical

1 Section 745A(b) of the FD&C Act requires submission of an eCopy for multiple submission types, including pre-submissions. FDA has interpreted this provision to include requests for feedback on medical device submissions of all types, including Study Risk Determinations, Early Collaboration Meeting requests, Informational Meeting requests, Submission Issue Meeting requests, and Day 100 Meeting requests.

Device Submissions"
(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf).

For products regulated in the Center for Biologics Evaluation and Research (CBER), respondents should consult CBER SOPP 8114: Administrative Processing of Documents Received Prior to Submitting Investigational or Marketing Applications (Pre-Application) (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079476.htm).

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency responsible for the collection of this information, and there are no requirements for the submission of similar information. Therefore, no duplication of data exists. No data exists from any source, other than the submitter requesting FDA Q-submission feedback, which can be used to provide FDA with information regarding planned clinical studies, IDEs, or marketing submissions for devices subject to FDA regulation.

5. Impact on Small Businesses or Other Small Entities

The information collection will have a minimal impact on a substantial number of small entities and may be helpful to small businesses that may not be able to afford a medical device consultant. FDA also aids small businesses by providing guidance and information through the Division of International and Consumer Education (DICE), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/MedicalDevices/default.htm. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

FDA estimates that approximately 40 percent of respondents are considered small businesses.

6. Consequences of Collecting the Information Less Frequently

This information collection is voluntary and at the discretion of the respondent and, as such, the information collected under the Q-submission Program cannot be collected less frequently. This program is intended to allow sponsors the opportunity to obtain targeted FDA feedback related to product development, including planned nonclinical evaluations, whether a clinical study is needed, proposed clinical study protocols, or data requirements prior to making a submission to the Agency. Such Q-Submissions are not required prior to a product submission, but are encouraged. It is the applicant's decision whether or not to submit a Pre-Submission or other type of Q-submission prior to submission of an IDE, 510(k), PMA, HDE, De Novo request, or CLIA categorization request. However, early interaction with FDA on planned nonclinical and clinical studies and careful consideration of FDA's feedback may improve the quality of subsequent submissions and facilitate the

development process for new devices.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.6

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.6.

8. Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of August 13, 2019 (84 FR 40069). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts in any manner or form will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondent

This ICR collects personally identifiable information (PII) or information of a personal nature. PII collected contains name, signature, phone number and email address. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity).

The guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with the Food and Drug Administration (FDA) regarding certain potential or planned medical device submissions, as well as issues conveyed in certain submission hold letters and IDE letters reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submissions Types and other uses of the Q-Submission Program.

FDA further determined this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information

collected.

Confidentiality of information submitted to FDA under the Q-submission Program is governed by the provisions of 21 CFR Parts 20. These provisions do not permit disclosure of information in a premarket notification submission that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden and Costs

The Q-Submission Program, as outlined in the guidance, covers different types of Q-Submissions available to request interactions with the FDA. These submissions include the following:

- Pre-Submission – A Pre-Submission is defined as a formal written request from an applicant/sponsor for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a formal written response followed by a meeting or teleconference in which any additional feedback or clarifications are documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation.
- Informational Meeting – An applicant/sponsor may request a meeting in which the intent is to share information with FDA without the expectation of feedback.
- Study Risk Determination – A study risk determination may be submitted to FDA when a sponsor, clinical investigator or Institutional Review Board (IRB) would like FDA's help in determining whether a planned clinical study is significant risk, and would require an IDE, or nonsignificant risk, and would not require an IDE.
- Formal Early Collaboration Meetings – The FD&C Act provides for two types of early collaboration meetings, agreement and determination meetings, which are intended to facilitate interaction between FDA and applicants and provide clear direction for testing and development of those devices requiring clinical investigations to support marketing. The FD&C Act makes it clear that the determinations or agreements resulting from these meetings are to be binding.
    - Determination meetings – A Determination Meeting, as described in section 513(a)(3)(D) of the FD&C Act, is available to anyone anticipating submitting a PMA or product development protocol (PDP) and is intended to provide the applicant with the Agency's determination of the type of valid scientific evidence that will be necessary to demonstrate that the

device is effective for its intended use. As a result of this meeting, FDA will determine whether clinical studies are needed to establish effectiveness and, in consultation with the applicant, determine the least burdensome way of evaluating device effectiveness that has a reasonable likelihood of success.

    - Agreement meetings – An Agreement Meeting, described in section 520(g)(7) of the FD&C Act, is open to any person planning to investigate the safety or effectiveness of a class III product or any implant, including submitters of 510(k)s for eligible devices. The purpose of this meeting is to reach agreement on the key parameters of the investigational plan (see 21 CFR 812.25), including the clinical protocol.
- Submissions Issue Request – A sponsor or applicant may request a Submission Issue Request to discuss deficiencies conveyed in a marketing submission (i.e. PMA, HDE, De Novo request, 510(k), Dual, or BLA) hold letter, a CW hold letter, an IDE letter, or an IND Clinical Hold letter.
- PMA Day 100 meetings – PMA Day 100 meeting requests are submitted by applicants for their original PMAs and Panel-track PMA Supplements to discuss the review status of their PMA application.

Each of these submission types will have a different recommended level of information commensurate with the type of feedback requested. Below is a summary of what the FDA generally recommends that all Q-Submission requests include; however, the details for each submission type are provided in the final guidance document:

- a cover letter that clearly identifies the Q-Submission type in the reference line (e.g., Submission Issue Request) and includes full contact information of the submitter as well as the correspondent if different from the submitter;
- a detailed device description;
- proposed intended use/indications for use of the product;
- proposed plan for clinical evaluation of the product or protocol for a planned clinical study, if applicable;
- a reference to any previous communications with FDA about the subject device including, but not limited to, any marketing submission and/or previous Q-Submission application numbers, and any other related documents, if applicable;
- a brief statement describing the purpose, scope, or objectives of the interaction with FDA;
- focused questions for which the applicant/sponsor is seeking guidance from FDA, if applicable;
- if a meeting is requested, the following information should be included:
    - the preferred meeting format (i.e., in-person or by teleconference);
    - a proposed agenda describing the topics or deficiencies for discussion and the estimated time for each agenda item;
    - three (3) or more preferred dates and times when the applicant/sponsor is available to meet given the guidelines in the final guidance for scheduling;

- the planned attendees or the type of subject matter experts the applicant/sponsor plans to invite so that FDA can ensure appropriate Agency experts are in attendance; and
- a list of any audiovisual equipment needed, such as conference phone or LCD projector.

12a. Annualized Hour Burden Estimate

Based on experienced trends over the past several years, an estimated 3,593 submissions are expected each year. FDA's administrative and technical staffs, who are familiar with the requirements for current Q-Submissions, estimate that an average of 137 hours is required to prepare a Q-Submission. There is a variance in the preparation submission because of the vast and varying complexities of medical devices.

The estimate of burden for this collection of information is shown in the following table:

Table 1.--Estimated Annual Reporting Burden [1]

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CDRH	3,502	1	3,502	137	479,774
CBER	91	1	91	137	12,467
TOTAL					492,241

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by regulatory affairs professionals.* FDA estimates the total annual cost to industry for a Q-Submission to be $35,441,352.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	492,241	$72	$35,441,352

* The estimated wage rate for a Regulatory Affairs Professional is based on The Regulatory Affairs Professional Society (RAPS) average total annual compensation of $150,422 for a U.S. regulatory affairs professional (https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US, p. 11, accessed 10/26/18). The hourly wage rate of $72 assumes a 40-hour work week and is rounded to the nearest dollar.

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no additional costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that a total of 90 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for participation in the Q-Submission Program.

Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE including benefits*), the estimated annual Federal cost is $24,327,450.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 143,713 hours. We attribute this adjustment to an increase in the number of submissions we received based on FY18 data.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.